

REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 57, 70, 83, and 96 have been amended herein for clarification purposes. Applicants believe that the amendments herein place the claims in better condition for appeal.

Claims 57, 66, 67, 70, 79, 80, 83, 92, 93, and 96 are currently pending. Reconsideration of the pending application is respectfully requested.

Claim Interpretation

The Examiner stated that claims 57, 70 and 83 do not state where the donor and acceptor fluorescent moieties are attached and, therefore, the Examiner interprets the claims as having the two labels at any of the primers and probes.

Applicants respectfully note that claims 57, 70 and 83 are directed toward articles of manufacture and do not require that the donor and acceptor fluorescent moieties be already attached to anything as provided. That is, the end user can attach the donor and acceptor fluorescent moieties to the appropriate sequence. As can be seen from dependent claims 66, 79, and 92, however, the articles of manufacture could be provided with the donor fluorescent moiety already attached to the first probe and the acceptor fluorescent moiety already attached to the second probe.

The 35 U.S.C. §103 Rejections

Claims 57, 66 and 67 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ramisse et al., Makino et al. and Buck et al. and further in view of Wittwer et al. and Qi et al.; claims 70, 79 and 80 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ramisse et al., Price et al., and Buck et al. and further in view of Wittwer et al. and Qi et al.; claims 83, 92 and 93 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ramisse et al, Bragg et al. and Buck et al. and further in view of Wittwer et al. and Qi et al.; and claim 96 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ramisse et al., Makino et al., Price et al., Bragg et al. and Buck et al. According to the Examiner, *In re Deuel* stands for the idea that

Applicants' claimed sequences are structural or functional homologs of oligonucleotides disclosed in one or more of the cited references and, therefore, are obvious over such disclosed sequences. The Examiner maintains this rejection despite the fact that Applicants' claimed sequences have a *different sequence* than the sequences disclosed in the cited references. This rejection is respectfully traversed.

For clarification purposes, Applicants have amended claims 57, 70, 83, and 96 to change "has the sequence ..." to "consists of the sequence ..." for each of the twelve sequences claimed. Applicants note that, on page 2 of the current Office Action, the Examiner stated that "even if the language was 'primer consisting of the sequence', the rejection would still be maintained as being obvious over prior art." Applicants respectfully request that these amendments be entered, however, because, as indicated above, Applicants believe this amendment places the claims in better condition for the appeal process.

Applicants reiterate the arguments from the Response to Office Action filed on February 16, 2007 and the Appeal Brief filed on July 21, 2005. Specifically, Applicants reiterate that Buck et al., which discloses primers for sequencing non-*Bacillus* nucleic acid, is not relevant to the predictability of the combination of two primers and two probes for real-time PCR amplification of *Bacillus anthracis*. In addition, Applicants reiterate that different sequences from, for example, the same gene are not considered to be structural or functional homologs of each other. Applicants believe the Examiner is misapplying *In re Deuel*.

The evidence already on the record regarding the unpredictability of designing and using primers and probes (see, for example, the University of Chicago Cancer Research Center DNA Sequencing Facility guidelines, Csordas et al., Elnifro et al., Tichopad et al., Abd-Elsalam, and Ballard et al., which were submitted in an Information Disclosure Statement filed with the February 16, 2007 Response to Office Action) clearly refutes the Examiner's allegations that "one of ordinary skill in the art would expect...primers...to work in amplification reactions with a reasonable expectation of success." Based on the evidence before the Examiner, one of ordinary skill in the art would not necessarily expect two primers and two probes to properly amplify and detect a target nucleic acid with 100% sensitivity and specificity, as is taught with the claimed primer and probe sequences.

Furthermore, Applicants reiterate that the claimed primers and probes exhibit high sensitivity and specificity toward their targets. Applicants respectfully refer the Examiner to Examples 4 and 5. Example 4 demonstrates the specificity that the claimed primers and probes have for a number of different *B. anthracis* strains, and Example 5 demonstrates that the claimed primers and probes exhibited no cross-reactivity with nucleic acids from 30 different species across a number of different genera.

In view of the amendments and remarks herein, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants respectfully request allowance of claims 57, 66, 67, 70, 79, 80, 83, 92, 93, and 96. Please apply the fee for the attached Petition for Three-Month Extension of Time and Notice of Appeal as well as any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

/July 22, 2008/

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Date: _____

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